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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,824	02/27/2001	David J Squirrell	63775US008	3738

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1656

NOTIFICATION DATE	DELIVERY MODE
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06/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 09/763,824	Applicant(s) SQUIRRELL ET AL.	
	Examiner David J. Steadman	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 106-162 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 110 and 111 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims allowed are

125, 126, 129, 130, 133, 134, 137, 138, 141, 142, 145, 146, 149, 150, 153, 154, 157, 158, 161 and 162.

Continuation of Disposition of Claims: Claims rejected are 106-109, 112-

124, 127, 128, 131, 132, 135, 136, 139, 140, 143, 144, 147, 148, 151, 152, 155, 156, 159 and 160.

DETAILED ACTION

Status of the Application

- [1] Claims 106-162 are pending in the application.
- [2] Applicant's amendment to the claims, filed on 4/28/08, is acknowledged. Claims 106-111 and 122 have been amended. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicant's arguments filed on 4/28/08 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [4] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

- [5] The objection to the amendment filed on 8/31/07 under 35 U.S.C. 132(a) as introducing new matter into the disclosure by listing "Xaa" in SEQ ID NO:39 of the sequence listing as being "Asp" is maintained for the reasons of record and the reasons set forth below. The objection was fully explained in a prior Office action. See particularly paragraph 9 beginning at p. 3 of the Office action filed on 11/28/07.

RESPONSE TO ARGUMENT: At p. 7 of the instant remarks, applicant argues the objection is obviated by amending claims 107 and 122 to replace "Asp" with "Asn".

Applicant's argument is not found persuasive. While the examiner acknowledges the instant amendment to claims 107 and 122, the objection is directed to the specification amendment filed on 8/31/07, not the claim amendment, which was separately addressed in a rejection under 35 U.S.C. 112, first paragraph. The only specification amendment filed on 8/31/07 is to enter a substitute sequence listing paper copy, wherein the sequence listing identifies "Xaa" in SEQ ID NO:39 as including "Asp", which does not appear to be supported by the application as filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, Second Paragraph

[6] The rejection of claims 106-120 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the claim amendment to replace "...amino acids described in..." in claims 106 and 109-111 with "...amino acid sequence set forth in...". Using claim 106 as an example, the examiner has interpreted the phrase "no more than 29 amino acids...are different" as meaning that the recombinant protein has an amino acid sequence with no more than 29 amino acid changes relative to the amino acid sequence of SEQ ID NO:38. It is noted that SEQ ID NO:38 itself requires that position 214 have a substitution at position 214 relative to wild-type *P. pyralis* luciferase.

Claim Rejections - 35 USC § 112, First Paragraph

[7] The new matter rejection of claims 107 and 122 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the claim amendment to replace “Asp” with “Asn”, which appears to find descriptive support in the specification at p. 7, third paragraph.

Double Patenting Rejection(s)

[8] The provisional obviousness-type double patenting rejection of claims 106-107, 109, 112-115, 118-120, 127, 131, 135, 139, 151, 155, and 159 as being unpatentable over claims 1-4, 6-10, 14-16, 18-19, 21, and 35-37 of co-pending Application No. 10/111,723 is maintained for the reasons of record and the reasons set forth below. The provisional rejection was fully explained in a previous Office action. See particularly paragraph 12 beginning at p. 5 of the 11/28/07 Office action.

RESPONSE TO ARGUMENT: Applicant requests the rejection be held in abeyance until the application is in condition for allowance and thus, the rejection is maintained.

Claim Rejections - 35 USC § 103

[9] The rejection of claims 106-108, 112-115, 118-123, 127, 131, 135, 139, 151, 155, and 159 under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (*J. Biol. Chem.* 272:18766-18771, 1997; “Thompson U”) in view of Thompson et al. (*Gene* 103:171-177, 1991; “Thompson V”), Hirokawa et al. (US Patent 6,074,859; “Hirokawa”) and Lowe et al. (US Patent 6,132,983; “Lowe”) is maintained for the reasons of record

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and the reasons set forth below. The rejection was fully explained in a previous Office action. See particularly paragraph 13 beginning at p. 7 of the 11/28/07 Office action.

[10] The rejection of claims 109, 124, 128, 132, 136, 140, 152, 156, and 160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson U in view of Thompson V, Hirokawa, and Lowe as applied to claims 106-108, 112-115, 118-123, 127, 131, 135, 139, 151, 155, and 159 above, and further in view of additional teachings of Thompson U and Lowe is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action. See particularly paragraph 14 beginning at p. 11 of the 11/28/07 Office action.

RESPONSE TO ARGUMENT: Beginning at p. 9 of the instant remarks, applicant argues:

Based on the cited references, it is not inherent that a *P. pyralis* mutant containing a mutation at position 214 would have activity or increased thermostability. None of the references made a mutation at this position. Thompson U establishes that mutations at adjacent or nearby residues can produce different results in a mutated protein. For example, *P. pyralis* luciferases having changes at amino acids 198, 201, 202, or 203 retained 10-100% of wild-type luminescent activity. See page 18767 of Thompson U. By the Examiner's rationale set forth in the office action on pages 10 and 13, it would be expected that luciferase containing a change at position 199 or 200 also would retain luminescent activity. However, changes at amino acids 199 or 200 resulted in a complete loss of activity. See page 18767 of Thompson U. Thus, the Examiner's rationale is misguided. In view of the above, one of ordinary skill in the art would not recognize the claimed subject matter to be inherent in the combination of cited references. The Examiner is requested to withdraw the rejection of claims 106-109, 112-115, 118-124, 127, 128, 131, 132, 135, 136, 139, '40, 151, 152, 155, 156, 159, and 160 under 35 U.S.C. §103.

Applicant's argument is not found persuasive. There appears to be no dispute that the combination of references provides motivation for making the claimed recombinant protein. What appears to be in dispute is whether or not an inherency rationale in a rejection under 35 U.S.C. 103(a) is proper because the prior art did not make a mutation at position 214 or recognize the resulting effects of a mutation at position 214. MPEP 2112 acknowledges that the inherent disclosures of a prior art reference can be relied upon in a rejection under 35 U.S.C. 103(a) and the inherent feature need not be known at the time of the invention. According to MPEP 2112, "The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. 'The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness.' *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995)". As such, a rejection under 35 U.S.C. 103(a) can be based upon an inherency rationale.

Also, MPEP 2112.I states, "[t]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)". See also MPEP 2112.II, which states, "There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact

inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). Thus, even though the prior art fails to expressly the resulting effects of a position 214 mutation, in view of the above noted MPEP guidance regarding inherency, such an express teaching need not be disclosed in the prior art.

The examiner acknowledges that the prior art does not appear to expressly teach a position 214 mutant or its resulting effects on luciferase activity and/or thermostability. However, the combination of cited prior art references clearly motivates one of ordinary skill to make a position 214 mutant, which appears to be undisputed by applicant. As acknowledged by the references of Thompson U, Thompson V, Hirokawa and Lowe, the prior art disclosed numerous attempts to improve properties of *P. pyralis* luciferase by mutation and mutagenesis. Although Thompson U suggests an Ala mutation in the region of 206-220 for reducing susceptibility to proteolysis, as noted by MPEP 2144.IV, "The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)".

According to MPEP 2112.IV, "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)... 'In relying upon the theory of inherency, the examiner must provide a basis

in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.’ *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)”. As noted in the previous Office action and reiterated above, the prior art reference of Thompson U expressly suggests Ala substitution at position 214. Since the specification acknowledges that Ala at position 214 enhances thermostability, the position 214 mutant as suggested by Thompson U would necessarily have such a characteristic, requiring no further modification or optimization to achieve the recited enhanced thermostability, which is an inherent feature of the polypeptide as suggested by Thompson.

MPEP 2112.01.I states, “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)”. Because the structure of the claimed polypeptide is the same as that suggested by Thompson U, it follows that the polypeptide as suggested by Thompson U necessarily has the required activity.

Therefore, at least for reasons of record and those set forth above, it is the examiner's position that the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention.

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[11] Claim(s) 116-117, 143, and 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson U in view of Thompson V, Hirokawa, and Lowe as applied to claims 106-108, 112-115, 118-123, 127, 131, 135, 139, 151, 155, and 159 above and further in view of Barnes (*PNAS* 87:9183-9187, 1990). Claims 116 and 143 limit the transformed cell of claims 114 and 135, respectively, to a plant cell. Claims 117 and 147 are drawn to a plant comprising the plant cell of claims 116 and 143, respectively.

The relevant teachings of the references of Thompson U, Thompson V, Hirokawa, and Lowe are set forth in the Office action filed on 11/28/07 beginning at p. 7. The combination of Thompson U, Thompson V, Hirokawa, and Lowe do not appear to teach or suggest a transformed plant cell or plant comprising said plant cell.

Barnes teaches an alternative method for determining luciferase activity using a transgenic plant recombinantly expressing a luciferase (see *Luciferin Assay* beginning at p. 9184, column 2, bottom).

Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Thompson U, Thompson V, Hirokawa, Lowe, and Barnes to transform a plant cell with a nucleic acid encoding *P. pyralis* luciferase with Ala at position 214 and test the luciferase activity of the resulting mutant by the method of Barnes. One would have been motivated to do this in order to identify a luciferase with greater stability in a plant, particularly as Thompson U teaches luciferase has a short half life *in vivo*. One would have a reasonable expectation of success to practice the method of mutating wild-type *P. pyralis* luciferase at position 214 to alanine by the method of Thompson U and test the resulting mutant by the method according to

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Barnes because of the results of Thompson U, Thompson V, Hirokawa, Lowe, and Barnes.

Therefore, claims 116-117, 143, and 147, drawn to a plant cell and plant as noted above, and method as described above would have been obvious to one of ordinary skill in the art at the time of the invention.

[12] Claim(s) 144 and 148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson U in view of Thompson V, Hirokawa, and Lowe as applied to claims 109, 124, 128, 132, 136, 140, 152, 156, and 160 above and further in view of Barnes. Claim 144 limits the transformed cell of claim 136 to a plant cell. Claim 148 is drawn to a plant comprising the plant cell of claim 144.

The relevant teachings of the references of Thompson U, Thompson V, Hirokawa, and Lowe are set forth in the Office action filed on 11/28/07 beginning at p. 7. The combination of Thompson U, Thompson V, Hirokawa, and Lowe do not appear to teach or suggest a transformed plant cell or plant comprising said plant cell.

As noted above, Barnes teaches an alternative method for determining luciferase activity using a transgenic plant recombinantly expressing a luciferase (see *Luciferin Assay* beginning at p. 9184, column 2, bottom).

Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Thompson U, Thompson V, Lowe, and Hirokawa to use the *Photinus pyralis* luciferase position 354 mutant as the “parent” polypeptide (in place of wild-type *Photinus pyralis* luciferase) for mutation at position 214 by the method of

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Thompson U, Lowe, or Hirokawa and test the resulting mutant by the methods according to Barnes. One would have been motivated to do this in order to identify a luciferase with greater stability in a plant, particularly as Thompson U teaches luciferase has a short half life *in vivo*. One would have had a reasonable expectation of success to use the *Photinus pyralis* luciferase position 354 mutant as the “parent” polypeptide (in place of wild-type *Photinus pyralis* luciferase) for mutation at position 214 because of the results of Thompson U, Thompson V, Lowe, Hirokawa, and Barnes.

Therefore, claims 144 and 148, drawn to a plant cell and plant as noted above, and method as described above would have been obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

[13] Status of the claims:

Claims 106-162 are pending.

Claims 106-109, 112-124, 127-128, 131-132, 135-136, 139-140, 143-144, 147-148, 151-152, 155-156, and 159-160 are rejected.

Claims 125-126, 129-130, 133-134, 137-138, 141-142, 145-146, 149-150, 153-154, 157-158, and 161-162 would appear to be in condition for allowance.

Claims 110-111 are objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
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